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## NEWS RELEASE

### **Axxess™ Self-Expanding Bifurcation DES Shown to be Safe and Effective up to Five Years**

**Paris, France, 23 May 2013** – New long-term data from the DIVERGE study, presented today at EuroPCR 2013 by Principal Investigator Dr. Stefan Verheye, Antwerp Cardiovascular Centre, ZNA Middelheim Hospital, Belgium, has shown that the use of the Axxess™ drug-eluting stent (DES) for the treatment of complex coronary bifurcation lesions resulted in low levels of both MACE and VLST over a five-year period. Axxess is now the only dedicated bifurcation stent with a substantial body of supporting data out to five years.

DIVERGE is a prospective, single-arm, multi-center study of 302 patients with de novo bifurcation lesions across 14 sites in Europe, Australia and New Zealand. It is the largest study conducted to date with a DES specifically designed for treating coronary bifurcation lesions. Following implantation of Axxess in the main branch, the side branch treatments were left at the operators' discretion. Additional conventional sirolimus-eluting stents (SES) were placed in 21.7% of the distal parent and/or side branch vessels. In 64.7% of the cases both branches were treated with an additional SES.

At five years post-procedure, 96.3% of patients originally enrolled in the study (291) were available for follow-up. The cumulative rate of MACE (a composite of death, MI and ischemia-driven TLR) was 21.3%. The occurrences of the individual components were 6.5% for death, 8.6% for myocardial infarction and 12.4% for ischemia-driven TLR.

Only five cases (1.7%) of very late definite stent thrombosis (VLST) were reported, all of which involved at least one SES. None of these very rare VLST events resulted in the death of a patient.

"These long-term results from DIVERGE are important because of the frequent presentation of bifurcation lesions in our daily clinical practice," commented Dr. Verheye. "These types of lesions are associated with higher complication and restenosis rates compared to conventional lesions. Axxess is now the only dedicated bifurcation stent with this level of supporting data out to five years."

Axxess is a self-expanding dedicated bifurcation stent which releases Biolimus A9™ [BA9™] from an abluminal biodegradable polymer coating. BA9 is an anti-restenotic drug designed by Biosensors specifically for use with stents. Axxess incorporates a conical-shaped self-expanding nitinol (nickel/titanium) stent platform, specifically designed to conform to the shape of the bifurcation anatomy. This has been tailored to reconstruct the bifurcation without creating a false carina (the ridge where the two vessels join), lowering the risk of uncovered struts at the flow divider.

Biosensors received CE Mark approval for Axxess in April 2011, supported by the positive nine-month results from the DIVERGE trial, which were published in the Journal of the American College of Cardiology (JACC) in March 2009. These demonstrated a very low in-stent restenosis rate of 6.4% in the overall bifurcation, and MACE rate of 7.6%, in patients treated with Axxess.

Axxess is currently available in many major markets worldwide [excluding the USA].

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#### **About Biosensors International Group, Ltd**

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Biosensors International develops, manufactures and markets innovative medical devices for interventional cardiology and critical care procedures. We aim to improve patients' lives through pioneering medical technology that pushes forward the boundaries of innovation.

With the increasing use of the BioMatrix™ family of drug-eluting stents and the recent launch of our Axxess™ self-expanding bifurcation drug-eluting stent, we are rapidly emerging as a leader in the global coronary stent market. The development of the BioFreedom™ drug-coated stent will further reinforce our market position.

All three stents incorporate Biolimus A9™ (BA9™), an anti-restenotic drug developed and patented by Biosensors specifically for use with stents. Both the BioMatrix stent family and the Axxess stent feature a unique abluminal biodegradable polymer coating, which fully degrades into carbon dioxide and water after six to nine months as it releases BA9. The BioMatrix stent family features workhorse stent platforms for a broad range of lesions, and the Axxess stent employs a self-expanding stent platform specifically designed for treating bifurcation lesions. BioFreedom, a completely polymer-free stent abluminally coated with BA9, received CE Mark Approval in January 2013.

For more information, please visit [www.biosensors.com](http://www.biosensors.com)